

Exhibit B

2001.01

MANUAL OF PATENT EXAMINING PROCEDURE

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.

(e) In any continuation-in-part application, the duty under this section includes the duty to disclose to the Office all information known to the person to be material to patentability, as defined in paragraph (b) of this section, which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

37 CFR 1.56 defines the duty to disclose information to the Office.

2001.01 Who Has Duty To Disclose

37 CFR 1.56. Duty to disclose information material to patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) Each inventor named in the application;
- (2) Each attorney or agent who prepares or prosecutes the application; and
- (3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

Individuals having a duty of disclosure are limited to those who are "substantively involved in the preparation or prosecution of the application." This is intended to make clear that the duty does not extend to typists, clerks, and similar personnel who assist with an application.

The word "with" appears before "the assignee" and "anyone to whom there is an obligation to assign" to make clear that the duty applies only to individuals, not to organizations. For instance, the duty of disclosure would not apply to a corporation or institution as such. However, it would apply to individuals within the corporation or institution who were substantively involved in the preparation or prosecution of the application, and actions by such individuals may affect the rights of the corporation or institution.

2001.03 To Whom Duty of Disclosure Is Owed [R-2]

37 CFR 1.56(a) states that the "duty of candor and good faith" is owed "in dealing with the Office" and that all associated with the filing and prosecution of a

patent application have a "duty to disclose to the Office" material information. This duty "in dealing with" and "to" the Office extends, of course, to all dealings which such individuals have with the Office, and is not limited to representations to or dealings with the examiner. For example, the duty would extend to proceedings before the Board of Patent Appeals and Interferences and the Office of the Commissioner for Patents.

2001.04 Information Under 37 CFR 1.56(a) [R-2]

37 CFR 1.56. Duty to disclose information material to patentability.

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is cancelled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misstatement. The Office encourages applicants to carefully examine:

- (1) Prior art cited in search reports of a foreign patent office in a counterpart application, and
- (2) The closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

The language of 37 CFR 1.56 (and 37 CFR 1.555) has been modified effective March 16, 1992 to emphasize that there is a duty of candor and good faith which is broader than the duty to disclose material information. 37 CFR 1.56 further states that "no

DUTY OF DISCLOSURE

2001.0.1

patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct."

The Office strives to issue valid patents. The Office has both an obligation not to unjustly issue patents and an obligation not to unjustly deny patents. Innovation and technological advancement are best served when an inventor is issued a patent with the scope of protection that is deserved. The rules as adopted serve to remind individuals associated with the preparation and prosecution of patent applications of their duty of candor and good faith in their dealings with the Office, and will aid the Office in receiving, in a timely manner, the information it needs to carry out effective and efficient examination of patent applications.

The amendment to 37 CFR 1.56 was proposed to address criticism concerning a perceived lack of certainty in the materiality standard. The rule as promulgated will provide greater clarity and hopefully minimize the burden of litigation on the question of inequitable conduct before the Office, while providing the Office with the information necessary for effective and efficient examination of patent applications. 37 CFR 1.56 has been amended to present a clearer and more objective definition of what information the Office considers material to patentability. The rules do not define fraud or inequitable conduct which have elements both of materiality and of intent.

The definition of materiality in 37 CFR 1.56 does not impose substantial new burdens on applicants, but is intended to provide the Office with the information it needs to make a proper and independent determination on patentability. It is the patent examiner who should make the determination after considering all the facts involved in the particular case.

37 CFR 1.56 states that each individual associated with the filing and prosecution of a patent application has a duty to disclose all information known to that individual to be material to patentability as defined in the section. Thus, the duty applies to contemporaneously or presently known information. The fact that information was known years ago does not mean that it was recognized that the information is material to the present application.

The term "information" as used in 37 CFR 1.56 means all of the kinds of information required to be

"material to patentability." Materiality is defined in 37 CFR 1.56(b) and discussed herein at MPEP § 2001.05. In addition to prior art such as patents and publications, 37 CFR 1.56 includes, for example, information on >enablement,< possible prior public uses, sales, offers to sell, derived knowledge, prior invention by another, inventorship conflicts, and the like. >"Materiality is not limited to prior art but embraces any information that a reasonable examiner would be substantially likely to consider important in deciding whether to allow an application to issue as a patent." *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1234, 66 USPQ2d 1481, 1486 (Fed. Cir. 2003) (emphasis in original) (finding article which was not prior art to be material to enablement issue).<

The term "information" is intended to be all encompassing, similar to the scope of the term as discussed with respect to 37 CFR 1.291(a) (see MPEP § 1901.02). 37 CFR 1.56(a) also states: "The Office encourages applicants to carefully examine: (1) prior art cited in search reports of a foreign patent office in a counterpart application, and (2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office." The sentence does not create any new duty for applicants, but is placed in the text of the rule as helpful guidance to individuals who file and prosecute patent applications.

It should be noted that the rules are *not* intended to require information *favorable* to patentability such as, for example, evidence of commercial success of the invention. Similarly, the rules are not intended to require, for example, disclosure of information concerning the level of skill in the art for purposes of determining obviousness.

37 CFR 1.56(a) states that the duty to disclose information exists until the application becomes abandoned. The duty to disclose information, however, does not end when an application becomes allowed, but extends until a patent is granted on that application. The rules provide for information being considered after a notice of allowance is mailed and before the issue fee is paid (37 CFR 1.97(d)) (see MPEP § 609, paragraph B(3)). The rules also provide for the

2001.05

MANUAL OF PATENT EXAMINING PROCEDURE

(A) because one or more claims are unpatentable (37 CFR 1.313(c)(1));

(B) for express abandonment so that information may be considered in a continuing application before a patent issues (37 CFR 1.313(c)(3)); or

(C) for consideration of a request for continued examination (RCE) under 37 CFR 1.114 (37 CFR 1.313(a) and (c)(2)). Note that RCE practice does not apply to utility or plant applications filed before June 8, 1995 or to design applications. See MPEP § 706.07(h).

See MPEP § 1308 for additional information pertaining to withdrawal of an application from issue.

In a continuation-in-part application, individuals covered by 37 CFR 1.56 have a duty to disclose to the Office all information known to be material to patentability which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application. See 37 CFR 1.56(e).

37 CFR 1.56 provides that the duty of disclosure can be met by submitting information to the Office in the manner prescribed by 37 CFR 1.97 and 1.98. See MPEP § 609. Applicants are provided certainty as to when information will be considered, and applicants will be informed when information is not considered. Note, however, that the Office may order or conduct reexamination proceedings based on prior art that was ~~not~~ cited/considered in any prior related Office proceeding. See MPEP § 2242 and MPEP § 2258.01<.

The Office does not believe that courts should, or will, find violations of the duty of disclosure because of unintentional noncompliance with 37 CFR 1.97 and 1.98. If the noncompliance is intentional, however, the applicant will have assumed the risk that the failure to submit the information in a manner that will result in its being considered by the examiner may be held to be a violation.

The Office does not anticipate any significant change in the quantity of information cited to the Office. Presumably, applicants will continue to submit information for consideration by the Office in applications rather than making and relying on their own determinations of materiality. An incentive remains to submit the information to the Office because it will result in a strengthened patent and will avoid later questions of materiality and intent to deceive. In addition, the new rules will actually facili-

tate the filing of information since the burden of submitting information to the Office has been reduced by eliminating, in most cases, the requirement for a concise statement of the relevance of each item of information listed in an information disclosure statement. It should also be noted that 37 CFR 1.97(h) states that the filing of an information disclosure statement shall not be considered to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR 1.56.

2001.05 Materiality Under 37 CFR 1.56(b)

37 CFR 1.56. Duty to disclose information material to patentability.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

(1) It establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or

(2) It refutes, or is inconsistent with, a position the applicant takes in:

(i) Opposing an argument of unpatentability relied on by the Office, or

(ii) Asserting an argument of patentability.

A *prima facie* case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

Under the rule, information is not material unless it comes within the definition of 37 CFR 1.56(b)(1) or (2). If information is not material, there is no duty to disclose the information to the Office. Thus, it is theoretically possible for applicants to draft claims and a specification to avoid a *prima facie* case of obviousness over a reference and then to be able to withhold the reference from the examiner. The Office believes that most applicants will wish to submit the information, however, even though they may not be required to do so, to strengthen the patent and avoid the risks of an incorrect judgment on their part on materiality or that it may be held that there was an intent to deceive the Office.

§ 1.56

MANUAL OF PATENT EXAMINING PROCEDURE

Dec. 28, 2001; effective Dec. 28, 2001; para. (c)(3) revised, 68 FR 14332, Mar. 25, 2003, effective May 1, 2003.

§ 1.56 Duty to disclose information material to patentability.

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is cancelled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

(1) Prior art cited in search reports of a foreign patent office in a counterpart application; and

(2) The closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

(1) It establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or

(2) It refutes, or is inconsistent with, a position the applicant takes in:

(i) Opposing an argument of unpatentability relied on by the Office, or

(ii) Asserting an argument of patentability.

A *prima facie* case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

(1) Each inventor named in the application;

(2) Each attorney or agent who prepares or prosecutes the application; and

(3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.

(e) In any continuation-in-part application, the duty under this section includes the duty to disclose to the Office all information known to the person to be material to patentability, as defined in paragraph (b) of this section, which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

[42 FR 5593, Jan. 28, 1977; paras. (c) & (e) - (j), 47 FR 21751, May 19, 1982, effective July 1, 1982; para. (c), 48 FR 2710, Jan. 20, 1983, effective Feb. 27, 1983; paras. (b) and (j), 49 FR 554, Jan. 4, 1984, effective Apr. 1, 1984; paras. (d) and (h), 50 FR 5171, Feb. 6, 1985, effective Mar. 8, 1985; para. (e), 53 FR 47808, Nov. 28, 1988, effective Jan. 1, 1989; 57 FR 2021, Jan. 17, 1992, effective Mar. 16, 1992; para. (e) added, 65 FR 54604, Sept. 8, 2000, effective Nov. 7, 2000.]